

REMARKS

In the Final Office Action mailed February 17, 2009, the Examiner took the following actions:

- (a) rejected claim 58 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement;
- (b) rejected claim 58 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention;
- (c) rejected claims 1, 6-8, 14, and 55-57 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,488,877 to Klein et al. ("Klein");
- (d) rejected claims 1, 6-8, 14, 55-58, and 61 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,810,721 to Mueller et al. ("Mueller");
- (e) rejected claims 15 and 16 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Klein; and
- (f) rejected claims 15 and 16 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Mueller.

By this reply, Applicant amends claims 1, 14-20, 31-35, 55, and 58. Claims 1, 6-9, 14-25, 27-36, 55-58, and 61 remain pending in this application. Of the pending claims, claims 9, 17-25, and 27-36 were previously withdrawn. No new matter has been added by this reply.

I. Examiner Interview

Initially, Applicant wishes to thank the Examiner for conducting the personal interview with Applicant's representatives, Roland G. McAndrews and Thomas Y. Ho, and inventor Frank Bonadio, on May 18, 2009. The discussion that follows is consistent with comments made during the interview. Also, the amended claim set includes changes in accordance with the suggestions that were made at the interview.

II. Rejection of claim 58 under 35 U.S.C. § 112, first paragraph

On page 2 of the Final Office Action, independent claim 58 was rejected under 35 U.S.C. § 112, first paragraph. Page 2 of the Final Office Action asserts that independent claim 58 contains new matter. For at least the reasons outlined below, Applicant requests reconsideration and withdrawal of the rejection.

Independent claim 58 now recites, *inter alia*, “[a] wound retractor system comprising . . . an insertion tool . . . wherein the insertion tool includes . . . a taper toward the longitudinal axis in a plane normal to a plane formed by the distal ring when the distal ring is in the engaged position.” As discussed at the interview, the recited features are shown in at least Figs. 43-46, which correspond to the elected embodiment. The recited plane corresponds to the plane of the paper in Figs. 43-46, and those figures depict an example of the recited taper. Thus, the recited features cannot constitute new matter. Moreover, the amendments to independent claim 58 are in accordance with what was discussed at the interview. For at least the above-outlined reasons, Applicant requests reconsideration and withdrawal of this rejection of independent claim 58.

III. Rejection of claim 58 under 35 U.S.C. § 112, second paragraph

On page 2 of the Final Office Action, independent claim 58 was rejected under 35 U.S.C. § 112, second paragraph. Page 2 of the Final Office Action asserts that independent claim 58 is indefinite. Applicant requests reconsideration and withdrawal of the rejection for at least the reasons outlined below.

Independent claim 58 now recites, *inter alia*, “[a] wound retractor system comprising . . . an insertion tool . . . wherein the insertion tool includes . . . a taper

toward the longitudinal axis in a plane normal to a plane formed by the distal ring when the distal ring is in the engaged position." As such, independent claim 58 now describes the taper in relation to the longitudinal axis of the insertion tool. Thus, in accordance with the discussion at the interview, the structural relationship described in the claim has been clarified. Accordingly, Applicant requests reconsideration and withdrawal of this rejection of independent claim 58.

IV. Rejection of claims 1, 6-8, 14, and 55-57 under 35 U.S.C. § 102(b) based on Klein

In light of the amendments to independent claims 1 and 55, and for the reasons outlined below, Applicant requests withdrawal of the rejection of claims 1, 6-8, 14, and 55-57 under 35 U.S.C. § 102(b), as anticipated by Klein.

A. Independent claim 1

Independent claim 1 has been amended, and now recites, *inter alia*,

[a] wound retractor system comprising:- a retractor having a retracting sleeve . . . and a distal portion including a portion of the retracting sleeve and a distal ring . . . and an insertion tool . . . including a groove configured to receive and hold the distal portion in an engaged position where the distal ring intersects a primary central longitudinal axis of the insertion tool, and the distal ring extends generally in a longitudinal direction with respect to the insertion tool.

Support for independent claim 1 can be found at least in Figs. 43-46 that correspond to the elected embodiment. The amendments to independent claim 1 have been made in accordance with the discussion during the interview.

Klein fails to disclose at least these features recited in independent claim 1.

Klein discloses an implant device including a rigid tubular device 10 and attached flexible sleeve member 12, where rigid tubular device 10 includes a ridge 46 held by a forceps during implantation and needle change operations. See Klein, column 2,

lines 60-62; and column 4, lines 5-8. With respect to the forceps, Klein states that "[a] suitable forceps tool for gripping ridge 44 is described in co-pending application, Serial No. 209,058, filed 11/21/80, the disclosure of which is incorporated herein by reference." Id. at column 4, lines 8-10. The co-pending application referred to in Klein is Martinez. In Martinez, a stem clamping forceps 100 includes arms 101 and 102 with grooves 105 and 106 for engaging a flange 42 of a stem 11. See Martinez, column 8, lines 50-61; and Figs. 14-18.

One of the deficiencies of Klein and Martinez is that they fail to disclose that grooves 105 and 106 in forceps 100 of Martinez are configured to receive and hold ridge 46 in an engaged position where a cuff 18¹ intersects a primary central longitudinal axis of forceps 100. See Klein, column 4, lines 5-8, and Fig. 1; and Martinez, column 8, lines 50-61, and Figs. 14, 15, and 18. Rather, Klein and Martinez disclose that grooves 105 and 106 are configured to receive and hold ridge 46 in a position where cuff 18 (located a distance away from ridge 46 and the primary central longitudinal axis of forceps 110) does not intersect the primary central longitudinal axis of forceps 110. See, e.g., Fig. 18 of Martinez. Thus, for at least the above-outlined reasons, Klein and Martinez fail to teach or even suggest "an insertion tool . . . including a groove configured to receive and hold the distal portion in an engaged position where the distal ring intersects a primary central longitudinal axis of the insertion tool," as recited in independent claim 1. Therefore Klein and Martinez fail to anticipate independent claim 1. Reconsideration and withdrawal of this rejection of independent claim 1 is therefore respectfully requested.

¹ Page 3 of the Office Action asserts that cuff 18 of Klein corresponds to a distal ring.

B. Independent claim 55

Independent claim 55 has been amended, and now recites, *inter alia*,

[a] wound retractor system comprising:- a retractor . . . wherein the retractor includes a distal portion; and an insertion tool . . . wherein the insertion tool includes a wound opening engaging portion consisting essentially of a monolithic shaft, the insertion tool further including a distal end portion including a retractor receiving portion, the retractor receiving portion including an opening facing distally away from the insertion tool.

Support for independent claim 55 can be found at least in Figs. 43-46, which correspond to the elected embodiment. The amendments to independent claim 55 have been made in accordance with the discussion at the interview.

Klein and Martinez do not disclose each and every feature recited in independent claim 55. One of the deficiencies of Klein and Martinez is that they fail to disclose an insertion tool including a wound opening engaging portion consisting essentially of a monolithic shaft. Rather, Martinez discloses forceps 100 that do not include a wound opening engaging portion (see, e.g., Fig. 18). Even if a portion of forceps 100 could somehow be interpreted as being a wound opening engaging portion, and Applicant does not agree that any portion can, such a portion would not be considered monolithic. Thus, Klein and Martinez fail to teach or even suggest “an insertion tool . . . wherein the insertion tool includes a wound opening engaging portion consisting essentially of a monolithic shaft,” as recited in independent claim 55.

Another of the deficiencies of Klein and Martinez is that while it is disclosed that arms 101 and 102 of Martinez include grooves 105 and 106, respectively, for receiving a ridge 46 on an implant device shown in Klein, neither groove 105 nor groove 106 is disclosed as facing distally away from forceps 100. See Klein, column 4, lines 5-8; and Figs. 14, 15, and 18 of Martinez. Since Martinez discloses that groove 105 of arm 101

does not face distally away from forceps 100, and that groove 106 of arm 102 is similarly deficient, Klein and Martinez fail to teach or even suggest, "the retractor receiving portion including an opening facing distally away from the insertion tool," as recited in independent claim 55. Accordingly, Klein and Martinez fail to anticipate independent claim 55. Reconsideration and withdrawal of this rejection of independent claim 55 is therefore respectfully requested.

C. Dependent claims 6-8, 14, 56, and 57

Claims 6-8, 14, 56, and 57 depend from one of independent claims 1 and 55, and are allowable for at least the reasons stated above that independent claims 1 and 55 are allowable. In addition, each of the dependent claims recites unique combinations that are neither taught nor suggested by the cited art, and therefore each is also separately patentable.

IV. Rejection of claims 1, 6-8, 14, 55-58, and 61 under 35 U.S.C. § 102(b) based on Mueller

In light of the amendments to independent claims 1, 55, and 58, and for at least the reasons outlined below, Applicant requests withdrawal of the rejection of claims 1, 6-8, 14, 55-58, and 61 under 35 U.S.C. § 102(b), as anticipated by Mueller.

A. Independent claim 1

Mueller discloses "a particularly advantageous retractor system 80 comprises retractor 81 and a delivery device including an obturator 88 having a longitudinal channel 89 with inward facing surfaces 90 which restrain the anchor ring therebetween." Mueller, column 10, lines 46-50. Mueller also discloses that "retractor 81 comprises an anchoring ring 82, tabs 84, and an outer ring 86. Tabs 84 have a tissue restraining portion 98 from which tethers 96 extend." Id. at column 10, lines 35-37.

But Mueller does not disclose a groove configured to receive and hold a distal portion of retractor 81. Rather, Mueller discloses a longitudinal channel 89, which receives the distal portion of retractor 81. See FIG. 10B in Mueller. Thus, Mueller fails to teach or suggest "the insertion tool including a groove configured to receive and hold the distal portion," as recited in independent claim 1. For at least this reason, Mueller fails to anticipate independent claim 1.

Even if longitudinal channel 89 could somehow be interpreted as being a groove, Mueller would still be deficient. This is because Mueller discloses that the distal portion of retractor 81 that is received in longitudinal channel 89 includes tethers 96, not a retracting sleeve. See Mueller, column 10, lines 35-37. Moreover, Mueller fails to disclose that tethers 96 or restraining portions 98 are attached substantially continuously around anchoring ring 82. See id. at Fig. 10C. Thus, Mueller also fails to teach or even suggest "the portion of the retracting sleeve being attached substantially continuously around the distal ring," as recited in independent claim 1. For at least this additional reason, Mueller fails to anticipate independent claim 1. The reconsideration and withdrawal of this rejection of independent claim 1 is therefore respectfully requested.

B. Independent claim 55

Obturator 88 of Mueller includes plate-like structures, one on each side of longitudinal channel 89. See Fig. 10B of Mueller, as well as column 10, lines 46-50. But neither of the plate-like structures includes an opening facing a wound opening during deployment of retractor 81. Thus, Mueller fails to teach or even suggest "the insertion tool includes a wound opening engaging portion consisting essentially of a

monolithic shaft, the insertion tool further including a distal end portion including a retractor receiving portion, the retractor receiving portion including an opening facing distally away from the insertion tool," as recited in independent claim 55. Accordingly, Mueller fails to anticipate independent claim 55. The reconsideration and withdrawal of this rejection of independent claim 55 is therefore respectfully requested.

C. Independent claim 58

As explained in column 10, lines 46-50 of Mueller, obturator 88 includes longitudinal channel 89, not a groove. Thus, Mueller fails to teach or suggest, "an insertion tool . . . wherein the insertion tool includes a groove for receiving the distal portion," as recited in independent claim 58.

Even if longitudinal channel 89 could somehow be interpreted as being a groove, Mueller would still be deficient. This is because Mueller does not disclose that obturator includes a taper toward its longitudinal axis in a plane normal to a plane formed by anchor ring 82 of Mueller in the engaged position of FIG. 10B. Rather, Mueller discloses that obturator 88 includes a taper (see the beveled portions at the lower end of obturator 88 in FIG. 10B) in a plane parallel to a plane formed by anchor ring 82 in the deployment position of FIG. 10B, and not toward its longitudinal axis. Thus, Mueller would still fail to teach or suggest, "a taper toward the longitudinal axis in a plane normal to a plane formed by the distal ring when the distal ring is in the engaged position," as recited in independent claim 58. Accordingly, Mueller fails to anticipate independent claim 58. The reconsideration and withdrawal of this rejection of independent claim 58 is therefore respectfully requested.

D. Dependent claims 6-8, 14, 56, 57, and 61

Claims 6-8, 14, 56, 57, and 61 depend from one of independent claims 1, 55, and 58, and are allowable for at least the reasons stated above that independent claims 1, 55, and 58 are allowable. In addition, each of the dependent claims recites unique combinations that are neither taught nor suggested by the cited art, and therefore each is also separately patentable.

V. Rejection of claims 15 and 16 under 35 U.S.C. § 103(a) based on Klein

In light of the amendment to independent claim 1, Applicant requests withdrawal of the rejection of claims 15 and 16 under 35 U.S.C. § 103(a) over Klein. As discussed above, Klein fails to teach or suggest each of the limitations in independent claim 1, from which claims 15 and 16 depend. Even if stem clamping forceps 100 of Klein could be modified with respect to its dimensions in the manner suggested on page 4 of the Office Action, such a modification would not remedy the deficiencies of Klein set forth in the above-outlined discussion of independent claim 1. Therefore, claims 15 and 16 are allowable at least for the same reasons that independent claim 1 is allowable.

VI. Rejection of claims 15 and 16 under 35 U.S.C. § 103(a) based on Mueller

In light of the amendment to independent claim 1, Applicant requests withdrawal of the rejection of claims 15 and 16 under 35 U.S.C. § 103(a) over Mueller. As discussed above, Mueller fails to teach or suggest each of the limitations in independent claim 1, from which claims 15 and 16 depend. Even if obturator 88 of Mueller could be modified with respect to its dimensions in the manner suggested on page 4 of the Office Action, such a modification would not remedy the deficiencies of Mueller set forth in the

discussion of independent claim 1. Therefore, claims 15 and 16 are allowable at least for the same reasons that independent claim 1 is allowable.

VII. Request for Rejoinder

Applicant requests that previously withdrawn claims 9, 17-25, and 27-36 be rejoined with the elected claims in this application. Claims 9, 17-25, and 27-36 all depend either directly or indirectly from independent claim 1, and thus, are allowable for at least the same reasons that independent claim 1 is allowable. In addition, each of these withdrawn dependent claims recites unique combinations that are neither taught nor suggested by the cited art, and therefore each is also separately patentable.

Conclusion

In view of the foregoing amendments and remarks, Applicant submits that this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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